(c) If no reports are submitted to either FDA or manufacturers during these time periods, no annual report is required.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4120, Jan. 26, 2000]

Subpart D—Importer Reporting Requirements

SOURCE: 65 FR 4120, Jan. 26, 2000, unless otherwise noted.

§ 803.40 Individual adverse event reporting requirements; importers.

(a) An importer shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 803.42 on FDA form 3500A as soon as practicable, but not later than 30 days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.

(b) An importer shall submit to the manufacturer a report containing information required by § 803.42 on FDA form 3500A, as soon as practicable, but not later than 30 days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the importer's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

§ 803.42 Individual adverse event report data elements.

Individual medical device importer reports shall contain the following information, in so far as the information is known or should be known to the importer, as described in § 803.40, which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Adverse event or product problem;

(2) Outcomes attributed to the adverse event, that is:

(i) Death;

(ii) Life threatening injury or illness;

(iii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iv) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of the event or problem to include a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Other relevant patient history including preexisting medical conditions.

(c) Device information (Block D) shall contain the following:

(1) Brand name;

(2) Type of device;

(3) Manufacturer name and address;

(4) Operator of the device (health professional, patient, lay user, other);

(5) Expiration date;

(6) Model number, catalog number, serial number, lot number or other identifying number;

(7) Date of device implantation (month, day, year);

(8) Date of device explantation (month, day, year);

(9) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and

(10) Concomitant medical products and therapy dates. (Do not list products that were used to treat the event.)

(d) Initial reporter information (Block E) shall contain the following:

(1) Name, address, and phone number of the reporter who initially provided information to the user facility, manufacturer, or distributor;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to FDA, if known.

(e) Importer information (Block F) shall contain the following:

(1) Whether reporter is an importer;

(2) Importer report number;

(3) Importer address;

(4) Contact person;

(5) Contact person's telephone number;

(6) Date the importer became aware of the event (month, day, year);

(7) Type of report (initial or followup (if followup, include report number of initial report));

(8) Date of the importer report (month, day, year);

(9) Approximate age of device;

(10) Event problem codes—patient code and device code (refer to FDA ''Coding Manual For Form 3500A'');

(11) Whether a report was sent to FDA and the date it was sent (month, day, year);

(12) Location, where event occurred;

(13) Whether a report was sent to the manufacturer and the date it was sent (month, day, year); and

(14) Manufacturer name and address; if available.

Subpart E—Manufacturer Reporting Requirements

§ 803.50 Individual adverse event reports; manufacturers.

(a) *Reporting standards.* Device manufacturers are required to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer:

(1) May have caused or contributed to a death or serious injury; or

(2) Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

(b) *Information that is reasonably known to manufacturers.* (1) Manufacturers must provide all information required in this subpart E that is reasonably known to them. FDA considers the following information to be reasonably known to the manufacturer:

(i) Any information that can be obtained by contacting a user facility, importer, or other initial reporter;

(ii) Any information in a manufacturer's possession; or

(iii) Any information that can be obtained by analysis, testing or other evaluation of the device.

(2) Manufacturers are responsible for obtaining and providing FDA with information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. Manufacturers are also responsible for conducting an investigation of each event and evaluating the cause of the event. If a manufacturer cannot provide complete information on an MDR report, it must provide a statement explaining why such information was incomplete and the steps taken to obtain the information. Any required information not available at the time of the report, which is obtained after the initial filing, must be provided by the manufacturer in a supplemental report under § 803.56.

[60 FR 63597, Dec. 11, 1995, as amended at 66 FR 23157, May 8, 2001]

§ 803.52 Individual adverse event report data elements.

Individual medical device manufacturer reports shall contain the following information, known or reasonably known to them as described in § 803.50(b), which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Adverse event or product problem;

(2) Outcomes attributed to the adverse event, e.g., death; or serious injury, that is:

(i) Life threatening injury or illness;